

(ii) Be capable of generating a log of all controlled substance prescriptions issued by a practitioner for a period specified by the practitioner upon request. Prescription information available from which to generate the log must span at least the previous two years.

(iii) Archive all logs generated.

(iv) Ensure that all logs are easily readable or easily rendered into a format that a person can read.

(v) Ensure that all logs are sortable by patient name, drug name, and date of issuance of the prescription.

(28) Where the electronic prescription application is required by this part to archive or otherwise maintain records, it must retain such records electronically for two years from the date of the record's creation and comply with all other requirements of § 1311.305.

§ 1311.125 Requirements for establishing logical access control—Individual practitioner.

(a) At each registered location where one or more individual practitioners wish to use an electronic prescription application meeting the requirements of this subpart to issue controlled substance prescriptions, the registrant(s) must designate at least two individuals to manage access control to the application. At least one of the designated individuals must be a registrant who is authorized to issue controlled substance prescriptions and who has obtained a two-factor authentication credential as provided in § 1311.105.

(b) At least one of the individuals designated under paragraph (a) of this section must verify that the DEA registration and State authorization(s) to practice and, where applicable, State authorization(s) to dispense controlled substances of each registrant being granted permission to sign electronic prescriptions for controlled substances are current and in good standing.

(c) After one individual designated under paragraph (a) of this section enters data that grants permission for individual practitioners to have access to the prescription functions that indicate readiness for signature and signing or revokes such authorization, a second individual designated under paragraph (a) of this section must use

his two-factor authentication credential to satisfy the logical access controls. The second individual must be a DEA registrant.

(d) A registrant's permission to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions must be revoked whenever any of the following occurs, on the date the occurrence is discovered:

(1) A hard token or any other authentication factor required by the two-factor authentication protocol is lost, stolen, or compromised. Such access must be terminated immediately upon receiving notification from the individual practitioner.

(2) The individual practitioner's DEA registration expires, unless the registration has been renewed.

(3) The individual practitioner's DEA registration is terminated, revoked, or suspended.

(4) The individual practitioner is no longer authorized to use the electronic prescription application (e.g., when the individual practitioner leaves the practice).

§ 1311.130 Requirements for establishing logical access control—Institutional practitioner.

(a) The entity within an institutional practitioner that conducts the identity proofing under § 1311.110 must develop a list of individual practitioners who are permitted to use the institutional practitioner's electronic prescription application to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions. The list must be approved by two individuals.

(b) After the list is approved, it must be sent to a separate entity within the institutional practitioner that enters permissions for logical access controls into the application. The institutional practitioner must authorize at least two individuals or a role filled by at least two individuals to enter the logical access control data. One individual in the separate entity must authenticate to the application and enter the data to grant permissions to individual practitioners to indicate that controlled substances prescriptions are

§ 1311.135

ready to be signed and to sign controlled substance prescriptions. A second individual must authenticate to the application to execute the logical access controls.

(c) The institutional practitioner must retain a record of the individuals or roles that are authorized to conduct identity proofing and logical access control data entry and execution.

(d) Permission to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions must be revoked whenever any of the following occurs, on the date the occurrence is discovered:

(1) An individual practitioner's hard token or any other authentication factor required by the practitioner's two-factor authentication protocol is lost, stolen, or compromised. Such access must be terminated immediately upon receiving notification from the individual practitioner.

(2) The institutional practitioner's or, where applicable, individual practitioner's DEA registration expires, unless the registration has been renewed.

(3) The institutional practitioner's or, where applicable, individual practitioner's DEA registration is terminated, revoked, or suspended.

(4) An individual practitioner is no longer authorized to use the institutional practitioner's electronic prescription application (e.g., when the individual practitioner is no longer associated with the institutional practitioner.)

§ 1311.135 Requirements for creating a controlled substance prescription.

(a) The electronic prescription application may allow the registrant or his agent to enter data for a controlled substance prescription, provided that only the registrant may sign the prescription in accordance with §§ 1311.120(b)(11) and 1311.140.

(b) If a practitioner holds multiple DEA registrations, the practitioner or his agent must select the appropriate registration number for the prescription being issued in accordance with the requirements of § 1301.12 of this chapter.

(c) If required by State law, a supervisor's name and DEA number may be

21 CFR Ch. II (4–1–12 Edition)

listed on a prescription, provided the prescription clearly indicates who is the supervisor and who is the prescribing practitioner.

§ 1311.140 Requirements for signing a controlled substance prescription.

(a) For a practitioner to sign an electronic prescription for a controlled substance the following must occur:

(1) The practitioner must access a list of one or more controlled substance prescriptions for a single patient. The list must display the information required by § 1311.120(b)(9).

(2) The practitioner must indicate the prescriptions that are ready to be signed.

(3) While the prescription information required in § 1311.120(b)(9) is displayed, the following statement or its substantial equivalent is displayed: "By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above."

(4) While the prescription information required in § 1311.120(b)(9) and the statement required by paragraph (a)(3) of this section remain displayed, the practitioner must be prompted to complete the two-factor authentication protocol.

(5) The completion by the practitioner of the two-factor authentication protocol in the manner provided in paragraph (a)(4) of this section will constitute the signing of the prescription by the practitioner for purposes of § 1306.05(a) and (e) of this chapter.

(6) Except as provided under § 1311.145, the practitioner's completion of the two-factor authentication protocol must cause the application to digitally sign and electronically archive the information required under part 1306 of this chapter.

(b) The electronic prescription application must clearly label as the signing function the function that prompts the practitioner to execute the two-factor authentication protocol using his credential.